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Used Equipment Guidance for Michigan's Food and Agriculture Industry

The acquisition of new food processing equipment is a significant investment for food processing facilities; thus, buying and selling of used or reconditioned equipment is a common occurrence. Careful consideration must be given prior to the purchase of used or reconditioned food processing equipment to prevent potential environmental or product contamination with bacteriological pathogens.

The following information is intended to strengthen a firm's understanding of what constitutes appropriate sanitary design as it relates to food processing equipment; assist in understanding the adequacy of used or reconditioned equipment; and provide information to help reduce the occurrence of pathogens in food manufacturing facilities.

What do you need from your next piece of equipment?

- What equipment requirements do you have?
- Are there any specific features you are looking for?
- What problems have you had previously with equipment? Look around to see what equipment is available to prevent these problems in the future.

Why should I be concerned about purchasing used or reconditioned equipment?

Used or reconditioned food equipment has been implicated in multiple recalls, foodborne illness outbreaks, and deaths due to contamination with bacteriological pathogens. In many cases, the equipment was not of sanitary design, allowing the pathogens to form resident niches and spread to ready-to-eat food products and other areas of the facility. The primary pathogens of concern are typically *Listeria monocytogenes* and *Salmonella spp*.

What is sanitary designed equipment?

https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2003/10-principles-of-equipment-design-for-ready-to-eat-processing-operations/

Equipment used in ready-to-eat processing areas must follow sanitary design principles. Although there are many expectations and standards present in multiple industries, if 10 primary principles of sanitary design are followed, coupled with good sanitary practices, it will decrease the likelihood of potential microbial harborage areas in the environment. Below are 10 principles of sanitary design for equipment in ready-to-eat processing areas:

- Cleanable to a micro-biological level. Equipment must be constructed and maintained to
 ensure it can be efficiently and effectively cleaned. The equipment not only has to be clean to
 sight and touch, but also must be free of pathogens and spoilage organisms.
- 2. **Made of compatible materials**. Equipment must be constructed of materials completely compatible with the product, environment, cleaning and sanitizing chemicals, and methods of sanitation. Materials must also be inert, corrosion resistant, non-porous and non-absorbent. Compatible materials will prevent corrosion and pitting which would provide a harborage area for microorganisms.
- 3. Accessible for inspection, maintenance, cleaning, and sanitation. All parts of the equipment should be assessable, and, if possible, disassembly should occur without the need of tools. When equipment is not cleaned in place (CIP), it must be assessable to cleaning. The four elements of successful cleaning are: mechanical action, temperature, a chemical

- treatment that will break the soil of concern, and time. If the processor can assess the soil, these elements can be better applied.
- 4. **No product or liquid collection**. Equipment must be self-draining to assure food product, water or other liquids do not accumulate or condense on the equipment or in product areas. Standing water can harbor both spoilage and pathogenic microorganisms.
- 5. Hollow areas hermetically sealed. Hollow areas of equipment must be eliminated or permanently sealed, but not by caulk. Areas such as frames, rollers, bolts, studs, end caps, mounting plates, sleeves, etc., must be continuously welded to the surface of the equipment, not attached via drilled and tapped holes. This is most easily addressed during the design phase. Eliminating or sealing these hollow areas will remove harborage areas for microorganisms.
- 6. **No niches**. Ensure equipment is free from pits, cracks, corrosion, open seams, lap seams, inside threads, bolt rivets, dead ends, recesses, etc. All welds must be smooth, continuous, and fully penetrating. Food processing equipment should not have any harborage points.
- 7. **Sanitary Performance**. During operations, the equipment must not contribute to unsanitary conditions or the harborage/growth of microorganism. This is linked to Principle #4. Allowing moisture and product build-up during a processing run increases the probability of increased microbial counts.
- 8. **Hygienic design of maintenance enclosures.** Maintenance enclosures (electrical panels, chain guards, pneumatic/hydraulic enclosures, etc.) and touch interfaces (push buttons, switches, touch screens, etc.) must be designed and maintained to ensure food and moisture does not penetrate or accumulate. This applies to both the surfaces of a device and to the connections.
- 9. **Hygienic compatibility with other plant systems**. Equipment must be designed to ensure hygienic compatibility with other equipment and systems (electrical, hydraulic, steam, air, water, etc.).
- 10. **Validate cleaning and sanitizing protocols.** Procedures for cleaning and sanitizing equipment should be clearly designed, written, and proven to be efficient and effective. Chemicals used in sanitization must be compatible with both the equipment and the manufacturing environment.

The Preventive Controls for Human Food rule in Subpart B (cGMPs) (21 CFR 117.40(a)(1)) requires that equipment and utensils be designed, and of such material and workmanship, as to be adequately cleanable.

- The equipment you purchase and use to process human foods, especially ready-to-eat (RTE) foods, must be designed and constructed to minimize sites where microbial harborage and multiplication can occur.
- If you plan to modify existing equipment, you or the manufacturer of the equipment should review the design of the modifications to ensure the modified equipment is designed and constructed to minimize sites where microbial harborage and multiplication can occur.
- When equipment is modified in place, or new or used equipment is installed in the establishment, there is an increased risk of contamination of food contact surfaces and food with Listeria monocytogenes.
- The food contact surfaces must be smooth, non-absorbent, sealed, and sloped to drain freely.
- Piping used to convey foods must not have dead ends or have cross-connections that could permit contamination to occur.

Source: (FDA) Control of Listeria monocytogenes in Ready-To-Eat Foods: (draft) Guidance for Industry

How do I determine if the equipment is of sanitary design?

- Conduct a physical examination of the equipment to determine conformance to the previously identified sanitary design characteristics.
- Identify, along with the previous owner, components that must be removed for sanitation or maintenance.
- Physically remove, or have removed for you, pieces of the equipment that are required to be dismantled when cleaning, sanitizing, or performing maintenance.
 - o Identify "hard to reach to clean" spots after you have dismantled the equipment.
- A few other things to consider:
 - Pumps: pumps that are not properly designed, cleaned, or maintained can become a source of pathogen harborage and cross-contamination.
 - Are pumps designed and intended for use in the food industry?
 - Is this the right pump for the intended use?
 - What was the pump previously used for?
 - When was the pump most recently completely dismantled to verify cleanliness?
 - Are the seals, bearings, impellers, lobes, shafts, and other components in good condition? Are the materials suitable for the intended use?
 - Bolts: Bolts and threaded bolt holes will harbor pathogens if not properly cleaned and are not permitted for food contact surfaces.
 - Are there exposed threaded bolts or threaded holes on the equipment?
 - Are bolts required to be removed during cleaning, sanitizing, or maintenance events?
 - What tools are required to perform cleaning and maintenance?
 - Have the pieces that require removal of bolts to dismantle been previously removed at appropriate frequency to ensure proper sanitation?
 - Seals and gaskets: If these are not removed during sanitation, they can harbor food residue underneath them, thus becoming a harborage site for pathogens.
 - Are they easily replaced?
 - How often are they replaced?
 - Are the seals in appropriate condition (not torn, pitted, pinched, etc.)?
 - Hoses: Verify the following:
 - Are the hoses made of food-grade material?
 - Is the material suitable for the food?
 - Are the hoses smooth and free of residues on the inside?
 - Are there any leaks?
 - Do the connections facilitate cleaning?
 - Are there exposed threads at the connections?
 - Are quick release connection gaskets in good repair?
 - o Equipment:
 - Location:
 - Is the equipment fixed in place or mounted on a table?
 - Does the underneath and base of the equipment have grooves, gaps, holes, etc., that provide niches where pathogens could survive?
 - Equipment usage:
 - Will it be in use at a Critical Control Point (CCP)/Preventive Control (PC) step in your process?
 - o Can it be calibrated, if necessary?
 - O When is the last time it was calibrated?
 - o Does it maintain calibration?
 - o Is there validation associated with the equipment (for CCP/PC)?

- Equipment construction:
 - Are there hollow parts, such as legs?
 - Are the welds sanitary, smooth and easily cleanable?
 - Are there cracks or crevices in conveyor belts, supports or food contact surfaces?
 - o Is corrosion/rust or discoloration of the metal present?

What is the history of the equipment? Has reconditioning been done?

When comparing reconditioned equipment, make sure to ask about the equipment's history and reconditioning. Find out all you can about how the equipment performed with its last owner, what issues there may have been, and what the seller had to recondition in order to get it back into operating condition.

- Why is the equipment being sold?
- Are you the original owner of the equipment?
 - o If no, who was?
- What food items were made using this equipment?
- Are there maintenance logs for work done on the equipment?
- Have there been modifications to the equipment?
- How long since the equipment has been used?
- Where has the equipment been stored?

What should I ask or look at when assessing used food processing equipment?

- How old is the equipment?
- Is the equipment visibly clean?
- What routine maintenance is required and how often?
 - Gaskets and seals?
 - When were they last removed from the equipment?
 - What do the surfaces under the gaskets and seals look like?
 - Are protective coverings, shrouds, guards, etc., present and are they removable for cleaning?
- How is the equipment cleaned during a sanitation cycle?
 - Clean-in-place or clean-out-of-place?
 - What parts must be removed during cleaning?
 - How are the parts washed?
 - O What chemicals are used?
 - Detergent
 - Sanitizer
- When was the equipment last cleaned during a sanitation cycle?
- Does the equipment have any documented environmental hazards associated with it (e.g., Listeria monocytogenes or Salmonella spp.)?

What can I do to reduce the likelihood of used equipment contaminating my food processing facility?

- Completely disassemble the equipment prior to cleaning and sanitizing. Clean and sanitize the equipment prior to installation on the production floor.
- At a minimum, thoroughly clean (with an appropriate detergent) and sanitize according to the manufacturer's (sanitizer) instructions.

What can I do to verify that my used or reconditioned equipment is free from contamination?

- Conduct rapid ATP or protein-based testing of the equipment to obtain the general hygienic condition of the equipment before use. Reclean and sanitize, as necessary.
- Conduct specific microbiological testing on smart locations of the equipment, to determine if a bacteriological pathogen is present on the equipment before use. Generally, you will want to test for *Listeria monocytogenes* or *Salmonella species*; however, testing for other pathogens may be done depending on the product produced. Be sure to note the exact location of each sample site, for tracking purposes.
 - o If a sample site is found to be positive for a pathogen:
 - Introduction of the equipment to your processing environment is highly discouraged. The pathogen could spread throughout the facility.
 - Conduct additional sampling in area of the positive sample site to determine the magnitude of the pathogen contamination.
 - Reclean, re-sanitize, and retest the sample site until multiple negative samples are realized. At least three negative samples from the original positive sample site are recommended.
 - It is recommended that you continue to monitor this area.
 - Is this area going to be continuously susceptible to contamination in the future?
- Create Sanitation Standard Operating Procedures (SSOP) for the equipment.
- Adequately train sanitation team members on the cleaning and sanitization of the equipment and periodically verify that they are appropriately carrying out this process.
- Document all employee training, including equipment specific training.

For more information, contact your food inspector or visit www.michigan.gov/MDARD.